



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------------|-------------|----------------------|---------------------|------------------|
| 10/759,303 | 01/20/2004 | Barry Lenard Reed | 025217-0122 | 7169 |
| 22428 | 7590 | 11/30/2007 | EXAMINER | |
| FOLEY AND LARDNER LLP | | | GEORGE, KONATA M | |
| SUITE 500 | | | ART UNIT | PAPER NUMBER |
| 3000 K STREET NW | | | | 1616 |
| WASHINGTON, DC 20007 | | | | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 11/30/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

**SUPPLEMENTAL
Office Action Summary**

| | | | |
|-----------------|------------------|--------------|-------------|
| Application No. | 10/759,303 | Applicant(s) | REED ET AL. |
| Examiner | Konata M. George | Art Unit | 1616 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 27 August 2007.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 36-44 and 46-66 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) 62-66 is/are allowed.
- 6) Claim(s) 36-44 and 46-61 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 20 January 2004 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 36-44 and 46-66 are pending in this application.

Request for Continued Examination (RCE)

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 27, 2007 has been entered.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on August 27, 2007 was noted and the submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner has considered the information disclosure statement.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 52, 53 and 61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants in the claims recite the phrase

"derivatives". Webster's Dictionary defines a derivative as "a substance derived from, or of such composition and properties, that it may be considered as derived from, another substance by chemical change, esp. by the substitution of one or more elements or radicals". Based on this definition it is unclear what the derivative is.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 36-44 and 46-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sunshine et al. (US 5,100,918) in view of Knight et al. (US 3,306,252).

Applicants claim an apparatus for applying a physiologically active agent to the dermal surface comprising a container and in said container an non-occlusive percutaneous or non-occlusive transdermal drug delivery system that comprises a therapeutically effective physiologically active agent, a dermal penetration enhancer and a volatile liquid to act as a vehicle.

Determination of the scope and content of the prior art

(MPEP §2141.01)

Sunshine et al. teach in column 10, lines 33-40 a topical composition comprising S(+) ibuprofen in an amount sufficient to prevent or treat ultraviolet radiation-induced erythema (0.5 to 10 wt%). The composition can contain suitable solvents or vehicles including ethanol, etc. (col. 9, lines 35-38). The topical composition can be combined with other types of sun-protective and/or anti-erythema topical agents such as sunscreens containing PABA ester (col. 10, line 49 through col. 11, line 10). Column 10, lines 1-20 teach topical ingredients that are present in commercial sunscreens such as preservatives and oils.

Ascertainment of the difference between the prior art and the claims

(MPEP §2141.02)

Sunshine et al. do not teach a container for the composition or that the delivery system provides metered doses and contains a shroud. It is for this that Knight et al. is joined.

Knight et al. disclose a shielded aerosol medicament dispenser for applying a medicament to a specific part of the body. The device comprises a vessel having a pressure chamber containing the fluid under pressure, a valve member and a hood mounted in a fixed axial position (col. 1, lines 36-52). It can be concluded from figure 1, that the nozzle of the device is placed perpendicular to the dermal surface. Examiner interprets the hood of Knight to be equivalent to the shroud of the instant invention.

Applicant describes the shroud on page 45, [0227] as "...envelope[s] the spray, providing an effective closed system, which deposits the active agent into the skin...". The hood portion of the device of Knight delivers the active agent in the same manner as claimed by applicant (see Fig. 1).

Finding of prima facie obviousness

Rational and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of Knight et al. (devices for the delivery of the composition an aerosol medicament dispenser) with the composition of Sunshine et al. (composition comprising an active agent and a sunscreen) to teach the claimed invention of a container comprising an active agent and a sunscreen and a container for the composition. With respect to the system providing meter doses, it is the position of the examiner that when the pumps of the aerosol and non-aerosol devices are depressed, the device delivers a metered dose of the composition to the patient.

Response to Arguments

5. Applicant's arguments filed December 4, 2006 have been fully considered but they are not persuasive.

Applicants argue that the composition of Sunshine et al. do not become dry to the touch within three minutes of application to the skin. It is the position of the examiner that "dry to the touch within three minutes of application to the skin" is

functional language and does not carry patentable weight. If the composition of Sunshine et al. is the same as what is claimed, it is presumed to have the same function. It is argued that Sunshine et al. do not teach a composition comprising a "penetration enhancer". While the composition of Sunshine et al. do not explicitly teach a "penetration enhancer", applicants' specification teaches that para-aminobenzoate compounds can be used as "penetration enhancers". Sunshine et al. disclose a composition comprising a physiologically active agent, a para-aminobenzoate compound and a volatile liquid, which reads on the claimed composition. Applicant argues that the composition containing at least 50% water does not become dry within three minutes of application. It is the position of the examiner that the claims don't limit the amount of water in the composition, therefore, any amount of water could be used with the expectation of achieving the desired results. If one of ordinary skill in the art wants a faster drying time then lowering the amount of water in the vehicle would be an obvious step.

Allowable Subject Matter

6. Claims 62-66 are allowed. The prior art does not teach, suggest or make obvious an apparatus for applying a metered dose of a non-occlusive percutaneous or non-occlusive transdermal drug delivery system to the dermal surface comprising a container, a metered dose applicator and wherein the container comprises a physiologically active agent, a volatile liquid and an penetration enhancer. It is not taught, suggested or made obvious that the active agent is selected from a hormone for

Art Unit: 1616

contraception, a progestogen other than progesterone, an oestrogen and progestogen other than progesterone or an oestrogen. The prior art is full of topical applications of hormones via, patches and creams. However, hormones delivered via a spray that becomes dry to the touch within three minutes are not taught by the prior art.

Conclusion

7. Claims 36-44 and 46-61 are rejected.

Telephone Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is 571-272-0613. The examiner can normally be reached from 8:00AM to 6:30PM Monday to Thursday.

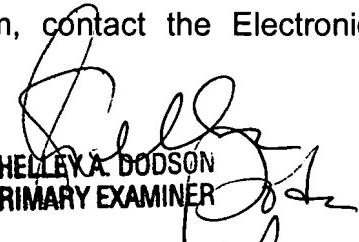
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter, can be reached at 571-272-0646. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300.

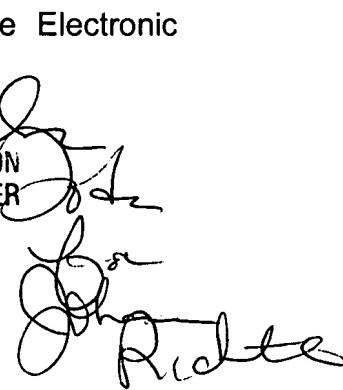
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

Art Unit: 1616

you have question on access to the Private Pair system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Konata M. George
Patent Examiner
Art Unit 1616


SHELLEY A. DODSON
PRIMARY EXAMINER


Johann R. Richter
Supervisory Patent Examiner
Art Unit 1616